



Virginia
Regulatory
Town Hall

Final Regulation Agency Background Document

Agency Name:	Department of Health (State Board of)
VAC Chapter Number:	12 VAC 5-185-10 et seq.
Regulation Title:	Policies and Procedures for Administering the Commonwealth Neurotrauma Initiative Trust Fund
Action Title:	Adopt regulations to Administer the CNI Program
Date:	December 18, 2000

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

These regulations will allow a new and important program to begin funding research into the mechanisms and treatment of neurotrauma, i.e., traumatic brain and spinal cord injury, and services for Virginians who have sustained neurotrauma. Specifically, these regulations will establish (i) policies and procedures for handling applications for funding received by the Commonwealth Neurotrauma Initiative (CNI) Advisory Board, (ii) criteria for reviewing applications, and (iii) procedures for distributing moneys from the CNI Trust Fund.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

No changes, other than strictly editorial changes, have been made to the text of this regulation since its publication.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On December 18, 2000, the State Health Commissioner, acting as vested with the authority of the State Board of Health pursuant to Section 32.1-20 of the Code of Virginia and in accordance with the bylaws of the Board, adopted the Policies and Procedures for Administering the Commonwealth Neurotrauma Initiative Trust Fund, 12 VAC 5-185-10 et seq. as a final agency regulation.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law.

Article 12 of Chapter 2 of Title 32.1 (Section 32.1-73.1 et seq.) of the Code of Virginia contains the law authorizing establishment of the Commonwealth Neurotrauma Initiative (CNI) Trust Fund, a special nonreverting fund, and the CNI Advisory Board, a permanent collegial body affiliated with the State Board of Health pursuant to Section 2.1-1.6 of the Code. Section 32.1-73.4 of the Code contains mandatory language authorizing the Board of Health to promulgate the proposed regulations.

These statutes may be viewed on the General Assembly Legislative Information System website at: <http://leg1.state.va.us/lis.htm>

Section 32.1-73.4 of the Code provides that the Board of Health "shall promulgate regulations establishing procedures and policies for soliciting and receiving grant applications [for moneys in the CNI Trust Fund] and criteria for reviewing and ranking such applications. . . . The Board [of Health] shall receive the recommendations of the [CNI] Advisory Board prior to promulgating or revising any such regulations."

(On August 25, 1999, the CNI Advisory Board voted to recommend to the Board of Health the policies and procedures embodied in the draft regulations, as then existent and as proposed by the Board of Health in September 2000. The CNI Advisory Board has considered all comments received during the public comment period that ended November 15, 2000, and recommends no changes to the regulation.)

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

Promulgation and adoption of the proposed regulations will help implement an unprecedented program in Virginia designed to promote medical research into traumatic brain and spinal cord injury and to provide treatment and care for Virginians who have sustained such injury.

Subsection B of Section 32.1-73.2 provides that: (i) moneys in the CNI Trust Fund "shall be used solely to support grants for Virginia-based organizations, institutions, and researchers" and (ii) "fifty percent [of the moneys in the Fund] shall be allocated for research on the mechanisms and treatment of neurotrauma and fifty percent shall be allocated for rehabilitative services."

Moneys are deposited into the CNI Trust Fund pursuant to Subsection E of Section 18.2-271.1 of the Code. That section provides that a fee of 105 dollars shall be charged "for reinstatement of the driver's license of any person whose privilege or license has been suspended or revoked as a result of . . . [a specified traffic violation]." This section further provides that 25 dollars of this fee "shall be transferred to the Commonwealth Neurotrauma Initiative Trust Fund."

This funding mechanism depends on fees generated by the reinstatement of drivers' licenses after those drivers have been convicted of offenses that carry the potential for causing motor vehicle collisions and associated neurologically-traumatic injuries. The funding mechanism rests on a sense of fairness and responsibility: Those in our society whose behavior often causes neurotrauma to befall others through the negligent or reckless driving of motor vehicles bear the cost of providing research into understanding and treating neurotrauma and

services for victims. The existence of the CNI Trust Fund also may have the indirect benefit of liberating certain general funds of the Commonwealth for other services and purposes.

The Trust Fund presently has a balance of approximately \$1.9 million. These moneys can be distributed to support the research and services contemplated by the authorizing law *only* when the proposed regulations to administer the CNI Trust Fund become fully effective.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

In their entirety, the proposed regulations will implement an innovative program to support medical research on the mechanisms and treatment of neurotrauma and to support rehabilitative services. Such a program has never before existed in Virginia. The text of the regulations consists of three articles.

Article 1 of the proposed regulations (sections 10 through 60) contains provisions that define key terms and set forth general information relating to administration of the CNI Trust Fund. These provisions include a statement of the general policy underlying and purpose of the regulations. They also discuss (i) the applicability of the Administrative Process Act (Section 9-6.14:1 et seq. of the Code of Virginia) to decisions that will be made pursuant to the proposed regulations, and (ii) the applicability of the Virginia Freedom of Information Act (Section 2.1-340 et seq. of the Code of Virginia) to applications submitted for grants from the CNI Trust Fund.

Article 2 (sections 70 through 100) of the proposed regulations sets forth the procedures by which the CNI Advisory Board will solicit and review applications for grants of moneys from the CNI Trust Fund. This article clearly sets forth the priorities with which the CNI Advisory Board will review applications for moneys for both medical research and rehabilitative services.

Article 3 (sections 110 and 120) of the proposed regulations specifies the considerations and criteria by which the CNI Advisory Board will rank and review applications for moneys in the CNI Trust Fund, and explains how the CNI Advisory Board will select successful applications, determine the amount of awards, and announce these decisions.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

One potential disadvantage identified during discussions of the CNI Advisory Board involves the possibility that certain public and private entities that presently provide ongoing rehabilitative services to disabled persons may abandon or limit their efforts to continue seeking general state funding, through the legislative process, for their programs in the belief that obtaining grants from the CNI Trust Fund may present an easier mechanism for funding.

The process of awarding grants from the CNI Trust Fund will necessarily involve a competitive process in which successful candidates may or may not, depending on the merits of any successive applications they submit, receive more than an initial award. Each award will cover a project designed to last one, two or three years. All entities that have received a grant from the CNI Trust Fund may seek an additional award to continue their projects or to engage in another worthy project, but their applications will be considered in the competitive process contemplated by the authorizing law and given form in the proposed regulations. Entities needing long-term funding for the rehabilitative services they provide should beware of the competitive nature of the manner by which the CNI Trust Fund will be administered and should consider carefully the advantages and disadvantages of any funding source available to them. No other disadvantages of the proposed regulations to the public, the agency or the Commonwealth have been identified.

The primary advantage of the proposed regulations to the public is the very creation of a heretofore nonexistent, specially-funded program that will support both important research on neurotrauma and needed services for Virginians who have sustained neurotrauma. By comparison, certain medical diseases and other medical conditions have long-established funding mechanisms and programs, both at the federal and state levels. Adoption of the proposed regulations will allow the CNI Trust Fund to fill a void, thereby serving the common good in an important new way.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

The State Board of Health received four comments during the public comment period that lasted from September 11, 2000, through November 15, 2000.

Summary of Public Comment:	Agency Response:
<p>1. Some portion of CNI moneys should be devoted to providing affordable, wheelchair-accessible housing.</p>	<p>While this is a laudable goal, the law specifies that half of the CNI moneys must go to research and half to providing “treatment and care,” or direct services. Applications for grants that, in part, propose housing amenities could lead to successful grants, but specifying in the regulations that a portion of the CNI moneys must be devoted to such a purpose would be in direct contravention of specific provisions in the law. (See Section 32.1-73.2 of the Code.)</p>

Summary of Public Comment (Cont'd):	Agency Response (Cont'd):
<p>2. The minimum amount of a successful grant should be lowered from \$5,000 to a smaller amount, perhaps as low as \$500. (See 12 VAC 5-185-110 B.)</p>	<p>While there are deserving objects of funding below the \$5,000 threshold, the CNI Advisory Board specified this minimum amount in order to prevent dilution of the program's effect and success, ensure a "critical mass" of resources for the successful implementation of each funded grant proposal, and maintain accountability by ensuring that the surveillance and tracking of (several rather than many) grantees' successes remains manageable.</p>
<p>3. (a) Prevention and (b) "outcome measures" should be a part of the program; (c) research into rehabilitation should be a goal. (This comment was not entirely clear in its substance.)</p>	<p>These are good suggestions, but (a) the General Assembly affirmatively removed prevention efforts as a category of activities to be funded by this program in 1998. The authorizing statute only allows funding of research and direct services; (b) outcome measures will certainly be used in ensuring the accountability and gauging grantees' success in carrying out their proposals; and (c) research into rehabilitation could be the focus of a successful grant application and project, but should not become a stated requirement or alternative in light of the breadth of the authorizing law specifying research and services as the targets of funding.</p>
<p>4. The discussion of rehabilitation in relation to "Option B" applications for funds should be broadened to include, not only medical and vocational aspects, but "independent living" aspects. (See 12 VAC 5-185-80.)</p>	<p>The Advisory Board carefully considered the authorizing law and discussed at length how best to define the "treatment and services," or direct services, portion of the program. The Advisory Board believes that the scope of acceptable Option B grants is broad enough to include the successful funding and implementation of grants aimed at rehabilitation for all purposes, including those that try to bring about "independent living."</p>

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

The agency is making no changes to the proposed regulations.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

In a broad and indirect sense, the successful implementation of the CNI program will benefit the institution of the family in discrete, actual instances across the Commonwealth by providing for the better treatment, care and self-sufficiency of traumatically-injured persons, whose families are undeniably affected by their injuries. This regulation will promote the better health of injured persons, thereby promoting the well-being and happiness of families across the Commonwealth.

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